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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,020	03/26/2004	Henry C. Lin	04-11US	7744
36814	7590 07/14/2005		EXAMINER	
NASTECH PHARMACEUTICAL COMPANY INC			SWARTZ, RODNEY P	
3450 MONTE VILLA PARKWAY BOTHELL, WA 98021-8906			ART UNIT	PAPER NUMBER
•			1645	,
		DATE MAILED: 07/14/2005		

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)			
	10/810,020	LIN, HENRY C.			
Office Action Summary	Examiner	Art Unit			
+ <sup>1 − 2</sup> ·	Rodney P. Swartz, Ph.D.	1645			
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address			
A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, however, may a reply be time within the statutory minimum of thirty (30) days will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	ely filed  will be considered timely. the mailing date of this communication.  O (35 U.S.C. § 133).			
Status					
1)⊠ Responsive to communication(s) filed on <u>Prelin</u> 2a)□ This action is <b>FINAL</b> . 2b)⊠ This     3)□ Since this application is in condition for allowar closed in accordance with the practice under E	action is non-final. nce except for formal matters, pro				
Disposition of Claims					
4) ⊠ Claim(s) 1-12 is/are pending in the application. 4a) Of the above claim(s) is/are withdray 5) □ Claim(s) is/are allowed. 6) ⊠ Claim(s) 1-12 is/are rejected. 7) □ Claim(s) is/are objected to. 8) □ Claim(s) are subject to restriction and/or	vn from consideration.				
Application Papers					
9)☑ The specification is objected to by the Examine 10)☑ The drawing(s) filed on 3-26-04 is/are: a)☑ accomplicant may not request that any objection to the objected to by the Examine 11)☐ The oath or declaration is objected to by the Examine	cepted or b) objected to by the drawing(s) be held in abeyance. See ion is required if the drawing(s) is obj	37 CFR 1.85(a). ected to. See 37 CFR 1.121(d).			
Priority under 35 U.S.C. § 119					
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>					
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	4) Interview Summary Paper No(s)/Mail Da	te			
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 1-19-05,1-26-05.	5)	atent Application (PTO-152)			

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#### **DETAILED ACTION**

1. Applicant's Preliminary Amendment, received 6December2004, is acknowledged.

2. Claims 1-12 are pending and under consideration.

## **Priority**

3. The priority statement at the beginning of the specification must be updated to reflect the current status of all applications.

#### Specification

4. The disclosure is objected to because of the following informalities:

Page 31, lines 2-3, there are blank spaces, is something to be added?

Appropriate correction is required.

## Claim Rejections - 35 USC § 112

- The following is a quotation of the second paragraph of 35 U.S.C. 112:
   The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 6. Claims 1-2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, last line, refers to "the action of (H)". It is unclear what is being referred to because there does not appear to be an "H". Claim 2 depends from claim 1, but does not clarify the issue.

7. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The claims are drawn to an active agent "peptide YY functional analogs". While the specification provides examples of such analogs, the specification does not define the metes and bounds of what actually constitutes a "peptide YY functional analog".

#### **Double Patenting**

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

- 9. Claims 1-12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,558,708.

  Although the conflicting claims are not identical, they are not patentably distinct from each other because the inventions claimed in the instant application are one of the embodiments claimed in the patent.
- 10. Claims 3 and 6 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 19 of copending Application No. 10/853,824. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to manipulating satiety in a subject comprising administering peptide YY or a peptide YY functional analog at an amount to alter satiety.

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This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting

claims have not in fact been patented.

**Conclusion** 

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner

should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571)

272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM

to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's

supervisor, Lynette F. Smith, can be reached on (571)272-0864.

The fax phone number for the organization where this application or proceeding is

assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR

system, see <a href="http://pair-direct.uspto.gov">http://pair-direct.uspto.gov</a>. Should you have questions on access to the Private

PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ODNEY P SWARTZ, PH.D PRIMARY EXAMINER

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June 22, 2005